

REMARKS/ARGUMENTS

This responds to the Office Action mailed December '10, 2004. Applicants have amended Claims 24-26, 28 and 42-45. Claims 46-47 have been canceled. Thus, Claims 24-30 and 42-45 remain pending in the application.

Objections to the Specification

The specification was objected to as failing to provide sufficient antecedent basis for the recitations of the pending claims. Applicants have amended the specification as set forth above to remedy the Examiner's objections. Applicants respectfully request reconsideration of these objections.

Objections to the Drawings

The Examiner objected to the drawings as including reference signs not mentioned in the detailed description portion of the specification. Applicants have amended the detailed description to specifically recite with references to the drawings an outer tube, an inner tube; a first septum; a second septum; a second lumen; a second aperture; and a third aperture. Applicants fail to understand the details of the rejection to the drawings. First, the only "reference signs" Applicants find on the drawings are *numerals*—not the text cited by the Office Action of an outer tube, an inner tube; a first septum; a second septum; a second lumen; a second aperture; and a third aperture. Applicants believe that all issues as to acceptance of the drawings are resolved by the proposed amendments to the specification set forth above. No new matter has been added. Otherwise, clarification as to specific reference numerals that are not mentioned in the specification is respectfully requested.

Nonelected Claims

Claims 30 and 43-45 have been withdrawn as being directed to a nonelected species of the invention, but will be allowable upon allowance of independent claim 24 and 42, respectively.

Accordingly, Applicants propose to amend withdrawn claims 30, and 43-45 since, upon allowance of a generic or linking claim (*e.g.*, independent claim 24 or independent claim 42, respectively), the withdrawn claims depending directly or indirectly therefrom in a non-elected species would also be allowable. Applicants further propose to amend claims 24-29, 31 and 42 as well as withdrawn claims 30 and 43-45 and respectfully request reconsideration of the application as amended.

Objections to Independent Claim 24

The Examiner indicates that Applicants failed to define and provide reference numerals for the claimed subject matter within the specification. (*See* Claim rejections- 35 U.S.C. § 112, page 4). Applicants have amended the specification as noted above. No new matter has been added. Applicants therefore respectfully request withdrawal of the objection to independent claim 24.

35 U.S.C. § 102(e)/35 U.S.C. § 103(a) Anticipation/Obviousness Rejections

Claims 24-29, 31, and 42 stand rejected under 35 U.S.C. § 102(e) or, alternatively, under 35 U.S.C. § 103(a) as being unpatentable over United States Patent No. 4,717,379 to Ekholmer (hereinafter “Ekholmer”). Applicants respectfully traverse this rejection, as hereinafter set forth.

As to anticipation, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

As to obviousness, M.P.E.P. 706.02(j) sets forth the standard for a Section 103(a) rejection:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

Ekholmer discloses a catheter probe for insertion into a body cavity. More specifically, the catheter is double-walled over a substantial portion of its length. Further, the catheter includes longitudinal partitions forming a multiplicity of separate longitudinal passages between the (two) walls. The passages are perforated from the outside of the catheter by a plurality of capillary holes. During use, a fluid, (*i.e.*, compressed air or liquid, or a cream or gel-like substance) can be introduced into at least some of the passages. Such a fluid is intended to provide a lubrication of the mucous membranes of the body cavity during insertion of the catheter. Thus, irritation

of the mucous membranes of the body cavity is avoided during insertion of the catheter and longer insertion periods are permitted without risk of infection.

Initially, Applicants note that amended claim 24 now recites, *inter alia*, “A triple lumen vascular access catheter for percutaneous entry into a blood vessel of the cardiovascular system of a patient by way of advancement along an insertion guide wire.”

Applicants respectfully submit that Ekholmer does not teach or suggest a catheter for percutaneous entry into a blood vessel. Further, Applicants respectfully submit that Ekholmer does not teach or suggest a catheter advanced along an insertion guide wire. No reference within Ekholmer teaches or suggests an insertion guide wire or the suitability of a catheter of the type taught therein for use therewith. Rather, Ekholmer teaches a catheter for insertion into a body cavity wherein the axial passages (3) are connected to a compressed air source or a fluid pressure, so that a lubrication of the outside of the catheter 1 can be obtained during the insertion thereof. Col. 1, lines 66-67; Col. 2, line 1.

Applicants recognize that the preamble of a claim may not be considered a limitation to a claim. Applicants respectfully submit, however, that where the preamble breathes life and meaning into the claim, it must be considered as a claim limitation. Further, the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. See, *e.g.*, *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963); M.P.E.P. § 2111.02. Applicants respectfully submit

that, since the recited purpose is recited in relation to structural aspects of a catheter and the recited purpose is in contradiction with the described operation of the structure of Ekholmer, it may clearly be appreciated that the structure of Ekholmer is different from the recited structure.

Still further, Ekholmer teaches that “[i]t is also possible to alternately connect the passages 3 to a pressure or suction source so that some of the passages 3 (*i.e.* every other one), is connected to a pressure source while the other passages 3 are connected to a suction source. In this way a draining of the washing agent and any possible secretion from the body cavity can be obtained.” Col. 2, lines 5-11.

Applicants respectfully submit that Ekholmer teaches away from a catheter having two lumens defined by a first and second septum extending between and separating an interior space an inner and outer tube.

Particularly, Ekholmer teaches and suggests that a multiplicity of passageways having a multiplicity of openings may be used for providing lubrication for insertion of the catheter within a body cavity or for draining or washing the body cavity. Thus, Applicants respectfully submit, the multiplicity of passageways and openings facilitate an even distribution of lubricant or flushing and cleaning.

Independent claim 24, as presently amended, recites, *inter alia*, “wherein the first septum and the second septum separate the interior space into a second lumen located on one side of a transverse cross section of the first septum, the inner tube, and the second septum, and a third lumen located on an opposite side of the transverse cross section of the first septum, the inner tube, and the second septum.” Applicants respectfully submit that Ekholmer does not disclose each and every element in as

complete detail as is contained in independent claim 24. Thus, Applicants assert that Ekholmer does not anticipate independent claim 24.

Further, Applicants respectfully submit that a second lumen located on one side of a transverse cross section of the first septum, the inner tube, and the second septum, and a third lumen located on an opposite side of the transverse cross section of the first septum, the inner tube, and the second septum may result in uneven distribution of lubricant or localized cleaning, both of which contradict the teachings of Ekholmer.

The Examiner contends that the catheter of Ekholmer may be used in combination with a guide wire, and specifically states that “it appears that the invention would perform equally well with a guide wire sized to fit into Ekholmer’s catheter.” Applicants respectfully disagree. First, Ekholmer does not teach or suggest a guide wire whatsoever. Further, Applicants respectfully assert that the use of a guide wire is inconsistent with the teachings of Ekholmer. Specifically, Ekholmer states, “[t]he object of the present invention is to provide a catheter, probe or the like which is easy to insert without irritating the mucous membranes...” Col. 1, lines 25-27. Thus, Applicants respectfully assert that one of ordinary skill in the art would not initially insert a guide wire into a body cavity for advancement of a catheter of the type taught by Ekholmer because doing so would irritate the mucous membranes that are specifically intended for protection by the catheter of Ekholmer. Summarizing, Applicants respectfully submit that one of ordinary skill in the art would not make the proposed modification to Ekholmer because to do so would be in direct disagreement with the purpose of the Ekholmer invention.

Accordingly, Applicants respectfully submit that dependent claim 24 is not obvious in view of Ekholmer. Applicants respectfully request reconsideration and allowance of independent claim 24.

Dependent claim 25, which depends from independent claim 24, is allowable for the same reasons claim 24 is allowable, as set forth above. Applicants respectfully request reconsideration and allowance of dependent claim 25.

In addition, dependent claim 25 recites, *inter alia*, “wherein the size of the inner diameter of the inner tube is about 0.04 inches.” The Examiner recognizes that Ekholmer does not anticipate dependent claim 25. As to obviousness, the background of Ekholmer references an urethral catheter. Accordingly, it is presumed that the catheter of Ekholmer relates primarily to an urethral catheter. Applicants respectfully submit that one of ordinary skill in the art would not modify the catheter taught by Ekholmer so that the inner diameter of the inner tube is sized to be about 0.04 inches, because to do so inhibits a reasonable expectation of success with respect to a suitable flow rate through such a catheter. Therefore, Applicants respectfully assert that a reasonable expectation of success has not been established for modifying the catheter taught by Ekholmer and that one of ordinary skill in the art would not be motivated to do so.

Dependent claim 26 should be allowable because it depends from independent claim 24, which should be allowable as explained above. Applicants respectfully request reconsideration and allowance of dependent claim 26.

Dependent claim 27 recites, *inter alia*, “wherein the first septum and the second septum are coplanar.” Also, dependent claim 27 is allowable as depending from

independent claim 24, which is allowable. Applicants respectfully request reconsideration and allowance of dependent claim 27.

Applicants note that independent claim 24 recites, *inter alia*, that “the first septum and the second septum separate the interior space into a second lumen located on one side of a transverse cross section of the first septum, the inner tube, and the second septum, and a third lumen located on an opposite side of the transverse cross section of the first septum, the inner tube, and the second septum.” Thus, Applicants respectfully submit that Ekholmer does not disclose, teach, or suggest a coplanar first and second septum that separates the interior space into a second lumen located on one side of a transverse cross section of the first septum, the inner tube, and the second septum, and a third lumen located on an opposite side of the transverse cross section of the first septum, the inner tube, and the second septum.

Dependent claim 28 is allowable as depending from independent claim 24, which is allowable. Applicants respectfully request reconsideration and allowance of dependent claim 28.

Dependent claim 29 is allowable as depending from independent claim 24, which is allowable. In addition, dependent claim 29 recites, *inter alia*, “each of the second lumen and the third lumen have a C-shaped transverse cross section.” Applicants respectfully submit that Ekholmer does not disclose, teach, or suggest a second and third lumen each having a C-shaped transverse cross section. Accordingly, Applicants respectfully request reconsideration and allowance of dependent claim 29.

Dependent claim 31 is allowable as depending from independent claim 24, which is allowable. Applicants respectfully request reconsideration and allowance of dependent claim 31.

Independent claim 42 recites, *inter alia*, “A triple lumen catheter for insertion into a patient by way of advancement along an insertion guide wire.”

As noted above, Applicants respectfully submit that Ekholmer does not teach or suggest a catheter advanced along an insertion guide wire and no reference within Ekholmer teaches or suggests an insertion guide wire or the suitability of a catheter of the type taught therein for use therewith. Specifically, Ekholmer states, “[t]he object of the present invention is to provide a catheter, probe or the like which is easy to insert without irritating the mucous membranes...” Col. 1, lines 25-27. Thus, Applicants respectfully assert that one of ordinary skill in the art would not insert a guide wire into a body cavity because doing so would irritate the mucous membranes that are specifically intended for protection by the invention of Ekholmer.

Thus, Applicants respectfully submit that Ekholmer does not disclose each and every element of independent claim 42 in as complete detail as is contained in the claim.

Additionally, independent claim 42 recites, *inter alia*, “a first lumen, the inner tube having an outer diameter less than an inner diameter of the outer tube, the inner tube positioned within the outer tube to define an interior space between the outer diameter of the inner tube and the inner diameter of the outer tube; a first septum extending between the outer diameter of the inner tube to the inner diameter of the outer tube; and a second septum extending between the outer diameter of the inner tube

and said the inner diameter of the outer tube, wherein the first septum and the second septum separate the interior space into a second lumen located on one side of a transverse cross section of the first septum, the inner tube, and the second septum, and a third lumen located on an opposite side of the transverse cross section of the first septum, the inner tube, and the second septum.

Further, Applicants respectfully submit that a second lumen located on one side of a transverse cross section of the first septum, the inner tube, and the second septum, and a third lumen located on an opposite side of the transverse cross section of the first septum, the inner tube, and the second septum may result in uneven distribution of lubricant or localized cleaning, both of which contradict the teachings of Ekholmer.


In summary, Applicants respectfully submit that one of ordinary skill in the art would not make the proposed modification to Ekholmer so as to render independent claim 42 obvious because to do so would be in direct disagreement with the teachings of Ekholmer. Therefore, Applicants respectfully request reconsideration and allowance of independent claim 42, as presently amended.

CONCLUSION

Applicants respectfully submit that claims 24-29, 31 and 42 should be in condition for allowance, and respectfully request a favorable action on the merits. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, Applicants request that he contact Applicants' undersigned attorney to expedite the handling of this application.

Respectfully submitted,

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